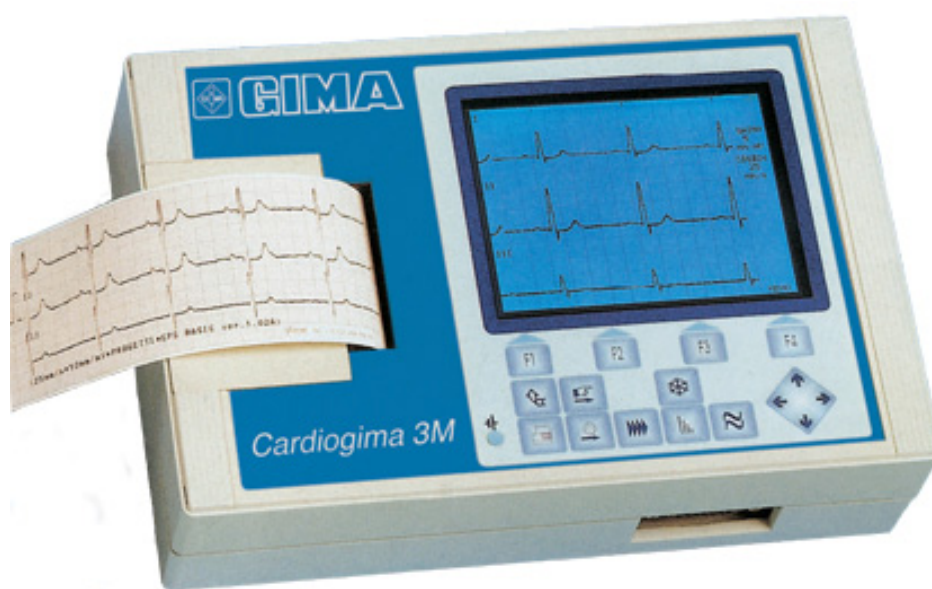




Code 33334 CARDIOGIMA 3M

**1-3 CHANNELS ELECTROCARDIOGRAPH
WITH GRAPHICAL DISPLAY, PRINTER AND INTERPRETATION**



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1. INTRODUCTION

2. CHARACTERISTICS AND SAFETY REFERENCES

3. USE INSTRUCTIONS

- 3.1 INITIAL SET-UP AND AMBIENT CONDITIONS
- 3.2 RECOMMENDATIONS FOR SAFE USE
- 3.3 POWER ON/OFF
- 3.4 KEY BOARD DESCRIPTION
- 3.5 DEFAULT OPERATIONAL SET-UP
- 3.6 THE MAIN OPERATIONAL MODES
- 3.7 SECONDARY OPERATIONAL MODES CHANGE
- 3.8 PREPARATION OF THE PATIENT
- 3.9 ELECTRODES APPLICATION
- 3.10 IMAGE FREEZING
- 3.11 PRINTING TRACES
- 3.12 LOADING THE THERMAL PAPER
- 3.13 BATTERIES CHARGE

4. MAINTENANCE

- 4.1 GENERAL RECCOMENDATIONS
- 4.2 PERIODIC CONTROLS

5. STANDARD ACCESSORIES

6. TROUBLE SHOOTING

1. INTRODUCTION

Congratulations on your purchase of the new CARDIOGIMA 3M electrocardiograph. The CARDIOGIMA 3M complies with the **Medical Devices Directive (93/42/EEC)** and therefore is labeled with the corresponding mark **CE 0068**.

2. CHARACTERISTICS AND SAFETY REFERENCES

CARDIOGIMA 3M is a 1-3 channels electrocardiograph and is in class **II CF** according to the **EN60601-1** and **EN60601-2-25** norms.

FUNCTIONAL CHARACTERISTICS

1. LCD Graphical Display 320x240 dots, 1 or 3 channels in Standard or Cabrera format with base line movement possibility.
2. High Resolution Thermal Printer (8 dots/mm). 1 or 3 channels hardcopy in real time with possibility to print the millimetric grid.
3. Manual or Automatic recording.
4. 10 seconds memory for all 12 derivations.
5. Image Freeze with the possibility to scroll into the memory for reviewing/hardcopy .
6. Integrated Digital Filters : Low pass, High pass and Notch 50/60 Hz .
7. Internal rechargeable Ni-Cd Batteries with high capacity and fast charge time.
8. Easy Operation with one touch keys and menus.
9. Based on a RISC processor for full digital signal processing.
10. Really portable. Small dimensions and light weight.

TECHNICAL CHARACTERISTICS

- POWER SUPPLY: Internal rechargeable Ni-Cd batteries
- LINE POWER SUPPLY: 220V~ $\pm 10\%$; 50 – 60Hz; 150 mA max;
Isolation CL2 B
- BATTERY AUTONOMY: 2,5 hours
- APPLIED PART: CF type
- INPUT IMPEDANCE: > 100 Mohm
- FREQUENCY RESPONSE: 0.05 : 145Hz
- CMRR: > 91 dB TIME CONSTANT: $> 3,2$ s
- ACQUISITION: 12 bit 800 samples/sec/channel
- LEADS : 12 Standard or Cabrera
- SENSITIVITY: 5mm/mV; 10mm/mV; 20mm/mV $\pm 5\%$
- SCROLLING SPEED: 5mm/s; 10 mm/s; 25 mm/s; 50 mm/s
- SIGNAL MEMORY: 10s for each lead
- PRINTER: thermal printer 8dots/mm, paper 58 mm
- DISPLAY: LCD 320 x 240 dots, back light CFL
- FILTERS: muscles tremors 35Hz digital; power line interferences
50Hz 60Hz digital; high pass 0.5Hz digital
- DEFIBRILLATION PROTECTION: internal
- DISPLAY/HARDCOPY: 1-3 channels
- DIMENSIONS: 240 x 160 x 65 mm
- WEIGHT : 1.500 g.
- CASE : IP 20
- OPERATION TEMPERATURE: $+10^{\circ}\text{C}$ 40°C
- STORAGE TEMPERATURE: -10°C 40°C
- RELATIVE OPERATIONAL UMIDITY: 25%95% without condensation
- CONFORMITY STANDARDS: 93/42/CEE; EN60601-1; EN60601-1-2 ;
IEC601-2-25
- CLASSIFICATION : II a class (according to 93/42/CEE)
- SERIAL NUMBER : model symbol, year, month and progressive production

3. USE INSTRUCTIONS

3.1 INITIAL SET-UP AND AMBIENTAL CONDITIONS

CARDIOGIMA 3M is built according to the CE standards and therefore is protected against electromagnetic interference from other devices. Nevertheless, in order to protect your device from other equipment that does not conform to the standards, it is recommended to:

- Avoid using cellular telephones in the vicinity especially during recording.
- Place the electrocardiograph as far as possible from electrical lines or static electricity sources to avoid the ECG signal disturbance.
- Avoid positioning of the electrocardiograph during recording, close to other diagnostic or therapeutic equipment like X-ray or ultrasound which can generate excessive electromagnetic interference.
- Perform the recording in a room with temperature between 20 and 25 degrees centigrade to avoid the patient feeling cold and induce the presence of muscle tremors.
- Do not expose the unit to excessive salty or humid environments.

3.2 RECOMMENDATIONS FOR SAFE USE

- Use the device in accordance with the instructions in this manual.
- The unit is delivered with a set of standard accessories. For reasons of safety, reliability and compatibility with the CE standards, use only the original accessories or others approved by the producer.
- CARDIOGIMA 3M is equipped with a thermal head printing mechanism which allows high quality hardcopy. To ensure the quality and reliability of the printer use only the original paper or one approved by the producer.
- Make sure that the line voltage corresponds to the voltage indicated on the batteries charger supplied with the unit.
- The CARDIOGIMA 3M has the isolation class **II CF** which means no ground connection is needed. Moreover the patient is fully isolated and defibrillation protected. The defibrillation protection is guaranteed only if the original patient cable is used.
- Check periodically the integrity of all accessories and the unit itself.
- Do not use the unit in presence of anesthetics or flammable gases.
- The producer is responsible for the unit in terms of safety, reliability and functionality only if:
 - The unit is used in accordance with the user instructions.
 - The electrical service at the location of use complies with the binding standards.

- The repairs are performed by the producer or by an authorized service center.
- The unit is equipped with long life rechargeable batteries. However it is recommended to use only the original charger and to follow the procedures described in this manual to ensure the long autonomy of the batteries.

The producer is not responsible for damage to persons or the unit following the usage of a non-original charger.

3.3 POWER ON/OFF

To turn on/off the instrument press the main switch, placed on its back left side. The initials screen will display the battery status bar.

If the charge value is lower than 80% please plug in the charger.

To start the work connect the patient cable, apply the electrodes on the patient and then push the key (start) F₁.

3.4 KEY BOARD DESCRIPTION



Batteries Charger Indicator



Paper Feed



Sequential Mode or Printing form Freeze



Manual Mode



Automatic Mode



Freeze



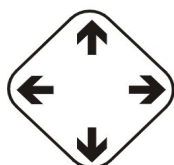
Paper Speed



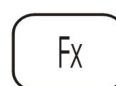
Sensitivity of Recording



Filters Menu



Vertical Arrows – Traces Group Selection



Horizontal Arrows - Memory Scroll

F1-F4 Menu Selections

3.5 DEFAULT OPERATIONAL SET-UP

At power on the default set-up is:

- Traces display/print number: 3
- Traces Order: Standard
- Paper Speed: 25 mm/s
- Sensitivity of recording: 5 mm/mV
- Filters: Disabled
- Traces Group: I; II; III
- Hardcopy frame length: 5 seconds

3.6 THE MAIN OPERATIONAL MODES

1. *Paper Speed*: 25mm/s at power on. By pushing the key **???** it is possible to select the paper speed: 50mm/s, 5mm/s, 10mm/s, 25mm/s..... 5mm/s
2. *Sensitivity of recording*: 5mm/mV by default. Pushing the key **{** it is possible to select the sensitivity of the trace: 10mm/mV, 20mm/mV.....5mm/mV.....
3. *Filters*: disabled by default. By pushing the key **≈** it is possible to enable the desired filter, according to the keys **F₁**; **F₂**; **F₃**:
 - **LP**: anti muscle tremors filter
 - **HP**: anti base line disturbs filter
 - **NOTCH**: anti power line disturbs filter
4. *Traces Group*: the Standard mode is predefined at power on. With this modality, on the display will show:
 - First Group: I; II; III
 - Second Group: aVr; aVL; aVF
 - Third Group: V₁; V₂; V₃
 - Fourth Group: V₄; V₅; V₆

It is possible to select the desired group by pushing the keys **▲** and **▼**.








Changing to *Cabrera modality*, the display will show:

- First Group: aVL; I; -aVR
- Second Group: II; aVF; III
- Third Group: V₁; V₂; V₃
- Fourth Group: V₄; V₅; V₆

3.7 SECONDARY OPERATIONAL MODES CHANGE

Using the menu options it is possible to access the secondary operational parameters as follows:

push the key **Menu (F₄)**, different menus will be displayed according to the keys **F₁; F₂; F₃**.

- First Menu:
 - *Standard (F₁)*: for turning on the Standard or Cabrera modality.
 - *Grid Off (F₂)*: for turning on/off the hardcopy grid.
 - *3 Leeds (F₃)*: for one or three traces display/print.
- Second Menu:
 - *Base 1 (F₁)*: enables the first trace base line shift using the  and  keys.
 - *Base 2 (F₂)*: enables the second trace base line shift using the  and  keys.
 - *Base 3 (F₃)*: enables the third trace base line shift using the  and  keys.
- Third Menu:
 - *Table (F₁)* : for turning on/off the Patient Data Table.
 - *Frame (F₂)*: to set the hardcopy frame length to 5/10 sec.
 - *Clamp (F₃)*: to reset the base lines when the electrodes are disconnected or in case of excessive shift of the traces.
 - Fourth Menu: for turning on the Filters as the key  alternative (v. Main operational modes).

3.8 PREPARATION OF THE PATIENT

For a high quality ECG recording good preparation of the patient and correct positioning of the electrodes is necessary.

- The patient should be relaxed and the room temperature must be above 20 deg. Centigrade in order to avoid the ecg signal to be disturbed by muscle tremors.
- Clean the skin where the electrodes will be placed with alcohol.
- Make sure that during recording the patient does not touch another person or conductive objects.

3.9 ELECTRODES APPLICATION

Apply a small quantity of conductive gel on the part of the skin where the electrodes will be placed (not necessary if disposable electrodes with pre-applied gel are used).

Position the electrodes according to the following scheme:

- C1: on the 4th intercostal space on the right parasternal part.
- C2: on the 4th intercostal space on the left parasternal part.
- C3: on the 5th rib, between C2 and C4.
- C4: on the 5th intercostal space, on the left hemiclavicular region.
- C5: on the left anterior axillary, at the same level as C4.
- C6: on the left mid-axillary at the level of C4.

Peripheral electrodes:


- N: Right leg
- R: Right hand
- F: Left leg
- L: Left hand




ECG DERIVATIONES ACCORDING TO IEC and AHA:

IEC	AHA
N Black	RL Green
R Red	RA White
C1 White/Red	V1 Brown/Red
C2 White/Yellow	V2 Brown/Yellow
C3 White/Green	V3 Brown/Green
C4 White/Brown	V4 Brown/Blue
C5 White/Black	V5 Brown/Orange
C6 White/Violet	V6 Brown/Violet
L Yellow	LA Black
F Green	LL Red



It is important not to use electrodes of different material as this can create polarization currents and disturb the base line of the ECG signals.

3.10 IMAGE FREEZING


By pushing the key “Freeze”  it is possible to stop the display. The data acquisition will continue for 10 seconds (RECORD).

When the acquisition is finished (MEMORY), through the  and  keys it is possible to review the traces memorized and to print them by pressing the key .

3.11 PRINTING TRACES



1. *Manual mode, in real time*: at any time, pressing the  “Manual key. To stop
→
the print push again the same key.
2. *Isochronous mode (suggested)*: pushing the key  the first leads group will be
→
printed and in the same time the other leads are acquired and printed in sequence for 5 or 10 seconds according to the frame length set-up.

Basic model

After first group print, the message “DATA FROM MEMORY” will be displayed. It is also possible to modify the parameters (paper speed, sensitivity of recording) and to reprint the traces in memory pushing the key “Copy” . To exit this mode press again the same key.

Parameter calculation/ Interpretation model

After traces hard copy, the table with parameter calculation will be printed (for Par. C. model) and then the interpretation (for Int. model). After machine, automatically, returns to normal operation.

3. *Sequential Mode*: push the key , all the electrocardiograph leads are acquired and printed in automatic sequence. The print can be stopped pressing the key  at any time.

3.13 LOADING THE THERMAL PAPER

When the thermal paper is finished, the “*paper missing*” message appears on the display. Cut the paper straight and insert it into the printer inlet window with the thermo sensible side down. The printer will feed it automatically.

Keep pushing the feed key until the paper comes out of the printer straight.

The paper used – of high quality – can be diagrammed or white; in this case it is necessary to program the electrocardiograph for the Grid Print (v. Secondary operational modes).

3.14 BATTERIES CHARGE

At the first utilization the batteries must be charged. During the first charge, it is suggested to turn off the instrument.

Connect the line power supply to the charge connector placed on the back side, near the main switch.

When the “*Battery Low*” message appears on the display it is necessary to recharge the batteries.

During charging the front LED is on. When the LED is flashing, or at maximum 4 hours time, disconnect the charger.

Batteries can also be charged connecting the optional cable to the car cigar-lighter.

It is a good practice to disconnect the charger, after charge finished

ATTENTION: use only the original line power supply.

4. MAINTENANCE

4.1 GENERAL RECCOMENDATIONS

The equipment needs neither special servicing nor calibration.

For a correct maintenance, is recommended:

- after use, clean the patient cables and the electrodes removing the gel residue
- do not use aggressive chemical detergents, or vapour.
- clean the unit with dry cotton.
- the device cannot be sterilized. The electrodes can be sterilized with oxide of ethylene.
- do not scratch the screen.
- do not spill liquid on the unit.
- do not pull the patient cables.

4.2 PERIODIC CONTROLS

Periodically control the battery status bar. When the charge value is lower than 80%, please plug in the charger.

IMPORTANT

To insure a correct and long-lasting operation of the batteries it is necessary to control the charge status. If the device is not used, it is suggested to recharge the batteries every 2 weeks.

5. STANDARD ACCESSORIES

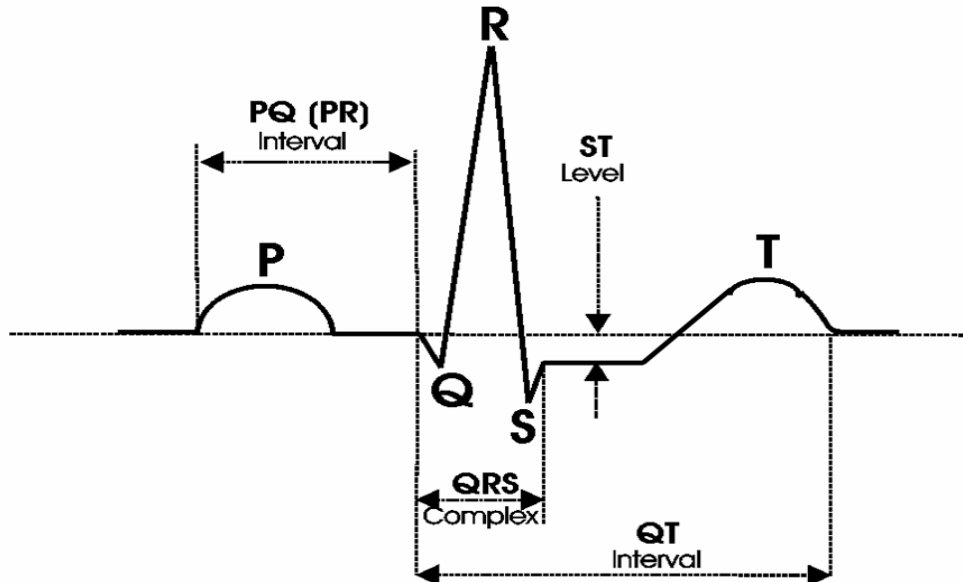
Carrying case (optional)
 Console CARDIOGIMA 3 M
 Patient Cable
 Electrodes Set
 Power Cable
 Paper roll
 Gel Flacon
 User Manual

6. TROUBLE SHOOTING

TROUBLES	CAUSES AND REMEDIES
Pressing the “Freeze” key the graphic does not stop	After pressing the “Freeze” key wait the cursor to reach the end of display, then press the other keys.
Graphic not displayed	Batteries discharged
Faded hardcopy	Non original paper or batteries discharged
No hardcopy	Wrongly positioned paper roll, thermosensitive side up.
Batteries not recharging	Verify power cable connection
Device does not turn on	Recharge the batteries
Faulty paper flow	End of paper roll, non original paper or wrongly positioned paper roll
Baseline drift	Dirty electrodes surface, insufficient skin contact or patient movement
Muscle tremors	Patient not relaxed; filter non active
Interferences on trace	Faulty patient cable; dirty electrodes surface or insufficient skin contact

PARAMETERS CALCULATION

STANDARD INTERVALS



RR: _____ The time between two consecutive QRS complexes, computed from the heart rate median value.

PQ (PR): _____ P-R interval is the time between the P wave start and the QRS complex start.

QRS: _____ The length of the QRS complex.

QT: _____ The interval between the QRS complex start and the end of the T wave.

QTC: _____ The normalized QT interval (QT that the patient would have at a 60BPM heart rate). The formula used for computing QTC is:

$$QTC = QT * \text{sqr}(1000 / RR)$$

WARNING

The electrocardiograms, in general the biosignals, do not correspond to precise mathematical functions. The measurement points defined by the machine are extremely sensitive to noise disturbs. For an accurate interpretation the doctor have to control and validate the measurement points.

The doctor should never confirm the machine analysis results without controlling first the morphology of the representative cycles and the correct position of the measuring points.

Each electrocardiogram and the relative analysis becomes a diagnostic document only after the doctor approval and his signature.